for syphilis, a statement that the plasma is reactive and must be used only for the manufacturing of positive control reagents for the serologic test for syphilis.

(10) Name, address, and license number of the manufacturer.

(11) The statement ''Negative by a test for antibody to HIV'', or equivalent statement.

(b) Source Plasma diverted for Source Plasma Salvaged shall be relabeled ''Source Plasma Salvaged'' as prescribed in §640.76. Immediately following the proper name of the product, the labeling shall conspicuously state as applicable, ''STORAGE TEMPERATURE EXCEEDED −20 °C'' or ''SHIPPING TEMPERATURE EXCEEDED −5 °C''.

[41 FR 10770, Mar. 12, 1976, as amended at 41 FR 27034, July 1, 1976; 41 FR 35062, Aug. 19, 1976; 47 FR 30969, July 16, 1982; 50 FR 4140, Jan. 29, 1985; 50 FR 35471, Aug. 30, 1985; 53 FR 117, Jan. 5, 1988; 63 FR 16685, Apr. 6, 1998]

§640.71 Manufacturing responsibility.

(a) All steps in the manufacture of Source Plasma, including donor examination, blood collection, plasmapheresis, laboratory testing, labeling, storage, and issuing shall be performed by personnel of the establishment licensed to manufacture Source Plasma, except that the following tests may be performed by personnel of an establishment licensed for blood or blood derivatives under section 351(a) of the Public Health Service Act, or by a clinical laboratory that meets the standards of the Clinical Laboratories Improvement Act of 1967 (CLIA) (42 U.S.C. 263a): *Provided,* The establishment or the clinical laboratory is qualified to perform the assigned test(s).

(1) The test for hepatitis B surface antigen.

(2) The total plasma or serum protein and the quantitative test for plasma or serum proteins or for immunoglobulins.

(3) The serologic test for syphilis.

(4) A test for antibody to HIV.

(b) Such testing shall not be considered divided manufacturing, which requires two product licenses for Source Plasma: *Provided,* That

(1) The results of such tests are maintained by the establishment licensed for Source Plasma whereby such results may be reviewed by a licensed physician as required in §640.65(b)(2) and by an authorized representative of the Food and Drug Administration.

(2) The Source Plasma manufacturer has obtained a written agreement that the testing laboratory will permit authorized representatives of the Food and Drug Administration to inspect its testing procedures and facilities during reasonable business hours.

(3) The testing laboratory will participate in any proficiency testing programs undertaken by the Center for Biologics Evaluation and Research, Food and Drug Administration.

[41 FR 10770, Mar. 12, 1976, as amended at 49 FR 23834, June 8, 1984; 50 FR 4140, Jan. 29, 1985; 53 FR 117, Jan. 5, 1988; 55 FR 11013, Mar. 26, 1990]

§640.72 Records.

(a) In addition to the recordkeeping requirements of this subchapter, the following records shall be maintained:

(1) Documentation compiled every 3 months establishing that the shipping temperature requirements of §600.15 of this title and §640.74(b)(2) are being met for Source Plasma intended for manufacture into injectable products.

(2) For each donor, a separate and complete record of all initial and periodic examinations, tests, laboratory data, interviews, etc., undertaken pursuant to §§640.63, 640.65, 640.66, and 640.67, except that negative test results for hepatitis B surface antigen, negative test results for antibody to HIV, and the volume or weight of plasma withdrawn from a donor need not be kept on the individual donor record: *Provided,* That such information is maintained on the premises of the plasmapheresis center where the donor's plasma has been collected.

(3) The original or a clear copy of the donor's written consent for participation in the plasmapheresis program or for immunization.

(4) The certification of the donor's good health as prescribed in §640.63(b)(3).

(5) If plasma that is reactive to a serologic test for syphilis is issued as prescribed in §640.65(b)(2)(iv), the distribution records shall indicate by number those units that are reactive.